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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mario Reyes Salinas

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THE WEBB LAW FIRM, P.C.

700 KOPPERS BUILDING

436 SEVENTH AVENUE

PITTSBURGH, PA 15219

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,316

Applicant(s)

SALINAS ET AL.

Examiner

SUSAN E. FERNANDEZ

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29, 33-35 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29, 33-35 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed July 8, 2009, has been received and entered.

Claims 1-20, 30-32, and 36-38 are canceled. Claims 41 and 42 are new.

Claims 21-29, 33-35, and 39-42 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganisms “Tr 115” and “Tr 116” are recited in claim 23, it is essential to the invention recited in that claim. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or

condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b), which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is directed to 37 CFR § 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
 - (1) The accession number for the deposit;
 - (2) The date of the deposit;

- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

It is noted that claim 23 also recites specific organism "T 22" (or referred to as KRL-AG 2 or Rifai). While this raises an issue with respect to enablement under 35 U.S.C. § 112, first paragraph, it appears that the microorganisms are publicly available without restriction. See http://www.epa.gov/opppbpd1/biopesticides/ingredients/factsheets/factsheet_119202.htm. The microorganisms are therefore considered to be publicly available, unless applicant indicates otherwise. Should applicant become aware of any information to the contrary during the prosecution of this case, applicant must disclose such information to the office.

Claims 21-29, 33-35, and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims generically recite compositions comprising fungi selected from variations of *T. harzianum*, *T. viridae*, *T. polysporum*, *T. longibratum*, and *T. koningi*, or methods of using or making said compositions. However, the specification does not contain an adequate description for the entire scope of this limitation.

MPEP § 2163 provides that:

The written description for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ..., reduction to drawings ..., or by

disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (Citation omitted.)

The recitation of variations of the above *Trichoderma* species generically encompasses any and all *Trichoderma* species given that the term “variation” is broad and can define fungi vastly different from the species, to the point where it defines species other than those recited in the claims. Moreover, claim 23 recites that the variation may be a “holomorph” which encompasses all fungi. According to Shenoy et al. (Fungal Diversity. 2007. 26: 1-54), “holomorph” is defined as “a fungus in its all meiotic (teleomorphosis) or mitotic (anamorphosis), sexual and asexual potential expressions of morphological nature and covers the unknown and known morphs of the fungus” (page 11, first paragraph). The only *Trichoderma* species described in the disclosure are *T. harzianum*, *T. viridae*, *T. polysporum*, *T. longibratum*, *T. koningii*, *T. harziano* and strains identified as T 22 (KRL-AG 2 or Rifai), Tr 115, and Tr 116. A holding of lack of written description over the recitation of fungi selected from variations of *T. harzianum*, *T. viridae*, *T. polysporum*, *T. longibratum*, and *T. koningii*, which encompasses any and all *Trichoderma* species, is clearly required.

Furthermore, the recitation in claim 21 of “a variation thereof” of the listed species is considered new matter. The second paragraph on page 8 of the specification lists the species *T. harzianum*, *T. viridae*, *T. polysporum*, *T. longibratum*, and *T. koningii*, and “variations of these obtained in the laboratory and identified as T 22, Tr 115, Tr 116, KRL-Ag 2 (Rifai), including

holoforms as *Hypocrea*, *Podostroma*.” Clearly the specification does not teach that the variations can be any and all strains, and the strains are instead limited to the strains T 22, Tr 115, Tr 116, KRL-Ag 2 (Rifai) and "holoforms as *Hypocrea*, *Podostroma*." While claim 23 specifies T 22, Tr 115, and Tr 116, it also recites "holomorph" which is not listed as a variation on page 8 of the specification. Therefore, the recitation "holomorph" is also considered new matter. Thus, claims 21-29, 33-35, and 39-42 are rejected under 35 U.S.C. 112, first paragraph.

Also considered new matter in claim 21 is the recitation "at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species." The applicant points to paragraph 33 of the published patent application for support, which is also the first full paragraph on page 6 of the specification as filed. However, this section specifies that only *Trichoderma longibratum* is exposed to radiation. Therefore, claims 21-29, 33-35, 39, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph. Though claim 41 indicates that *T. longibratum* is "the *Trichoderma* species that is exposed to radiation," parent claim 21 requires that "at least one of the *Trichoderma* species" is exposed to radiation. Thus, claim 41 can encompass irradiated *Trichoderma* species besides *T. longibratum*, requiring claim 41 to also be rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-29, 33-35, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite since it is unclear what would be considered “variations thereof” of the species recited. The “variations” of the recited species could even be considered any other *Trichoderma* species. Thus, claims 21-29, 33-35, and 39-42 are rejected under 35 U.S.C. 112, second paragraph.

Claim 29 is confusing since it is unclear what is defined by a “cicatrizing paint.” It does not appear to be a recognized term of the art. If, as the applicant asserts, the “cicatrizing paint” is a paint capable of wound healing, it is unclear how there can be a latex for “pruning” it. It is noted that in the prior art, there are “pruning paints” which cover pruning wounds of trees. See column 1, lines 18-23 of Sedun (US 5,395,851).

Claim 41 is rendered indefinite by the recitation “*T. longibratum*” which lacks antecedent basis since parent claim 21 instead refers to “*T. longibrachiatum*”. Note also that the specification as filed recites throughout “*T. longibratum*.” However, it appears that the specification is actually referring to “*T. longibrachiatum*” due to its discussion about NZ 335107 teaching a *T. longibratum* culture. The abstract of NZ 335107 (listed in IDS filed 3/7/06), discusses a culture of *T. longibrachiatum* (abstract).

Claim 41 is also rendered indefinite by the recitation “the *Trichoderma* species that is exposed to radiation.” Parent claim 21 indicates that “at least one of the *Trichoderma* species” is exposed to radiation. Therefore, in the case where more than one species is irradiated, it is unclear which of the species is considered “the *Trichoderma* species.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-23 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCabe et al. (US 4,828,600) in view of Papavizas (US 4,489,161) and Harman (Plant Disease. 2000. 84(4): 377-393).

McCabe et al. discloses a fungal inoculant that may comprise a mixture of *Trichoderma hamatum* and *Trichoderma harzianum* (column 2, lines 38-42) and that the strains included in this mixture were “isolated natively from the field” (column 2, lines 43-44). See also column 5, lines 46-50. Furthermore, the strains in the mixture could be corn yield mutations of the specific strains of *Trichoderma hamatum* and *Trichoderma harzianum* disclosed in McCabe et al. (claim 1). *T. hamatum* can be considered a “variation” of *Trichoderma* species *T. viridae*, *T.*

polysporum, *T. longibratum*, or *T. koningii*, since *T. hamatum* is a species of the same genus as the fungi listed above, the term “variation” is broad, and since “holomorph” in instant claim 23 encompasses all fungi. Therefore, McCabe et al. meets limitations in instant claims 21-23. The McCabe fungal inoculant is a fungicidal composition (column 3, lines 6-14) and may include a carrier (column 3, lines 34-35). Furthermore, the inoculant may be inserted into the furrows into which corn is planted (thus applied to soil) or coated directly on corn seeds. See column 3, lines 34-39. Thus, limitations in instant claim 35 (since corn seeds are food) are taught by the reference.

McCabe et al. differs from the claimed invention in that it does not expressly disclose that at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species.

Papavizas discloses that new strains and biotypes of *Trichoderma viride* and *Trichoderma harzianum* have been developed that are resistant to certain fungicides by exposing them to gamma/ultraviolet radiation (column 1, lines 13-21).

At the time the invention was made, it would have been obvious to have exposed any of the *Trichoderma* species of McCabe et al. to radiation prior to combining them to create the fungal inoculant. One of ordinary skill in the art would have been motivated to do this since it would have resulted in strains more resistant to other fungicides, including any fungicides possibly released by any of the other *Trichoderma* species.

Note further that the claims are product-by-process claims. MPEP 2113 indicates that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”” The strains that would have been obtained by radiation exposure of the strains of *Trichoderma hamatum* and *Trichoderma harzianum* disclosed by McCabe et al would have been expected to be similar (thus render obvious), if not be the same, as the corn yield mutated fungi disclosed in claim 1 of McCabe et al. Therefore, if McCabe et al. were not combined with Papavizas, the instant claims would still be considered unpatentable even though the prior product was made by a process not involving radiation.

McCabe et al. also differs from the claimed invention in that it does not expressly disclose that the biological inoculant comprises *Trichoderma* strains wherein the strains are identified as T 22 (KRL-AG 2 or Rifai), Tr 115, or Tr 116.

Harman discloses the *T. harzianum* strain T-22 organism, which is also known as KRL-AG2 (page 377, second column, second paragraph). This biocontrol agent controls the growth of fungi, thereby serving as a suitable substitute for other fungicides and as an agent for plant growth (page 385, first column and Figures 9 and 10).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the *T. harzianum* strain used in the McCabe invention with the *T. harzianum* strain disclosed by Harman. One of ordinary skill in the art would have been motivated to do this since *T. harzianum* strain T-22 is effective against fungi and improves plant growth, thus sharing properties with the *T. harzianum* strain of the McCabe invention. Moreover, the strains are members of the same species, thus sharing other properties. One of

ordinary skill would have reasonably expected that the substitution would have been suitable as a component in a biological inoculant for improving plant growth.

In sum, claims 21-23, and 35 are rendered obvious. A holding of obviousness is clearly required.

Claims 21-23, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paau et al. (US 5,194,258), Hermosa et al. (Applied and Environmental Microbiology, 2000, 66(5): 1890-1898), and the ATCC catalog in view of Papavizas and Harman.

Paau et al. discloses a method of protecting crop plants from fungal plant disease wherein a culture of biocontrol fungus comprising a mixture thereof of *Trichoderma* and *Gliocladium virens* is used. See abstract and claim 1 (particularly part (a)). *Gliocladium virens* is also known as *Trichoderma virens* (Hermosa et al., page 1890, first column, last paragraph). Moreover, in the discussion of *Trichoderma* strains used as biocontrol fungus (column 6, lines 64-66), the strains specified are under the ATCC numbers 24274 and 32247, and are strains of *Trichoderma harzianum* ("ATCC Number: 24274" and "ATCC Number: 32247", <http://www.atcc.org/common/catalog/numSearch/numResults.cfm>, accessed February 22, 2006). *T. virens* can be considered a "variation" of *Trichoderma* species *T. viridae*, *T. polysporum*, *T. longibratum*, or *T. koningii*, since *T. virens* is a species of the same genus as the fungi listed above, the term "variation" is broad, and since "holomorph" in instant claim 23 encompasses all fungi. Thus, Paau et al. teaches a mixture of *Trichoderma harzianum* and a variation thereof of the species listed in instant claim 21. Therefore, limitations in instant claims 21-23 are taught by

Paau et al. Since the biocontrol fungus can be applied to seeds which are considered food, Paau et al. also teaches limitations in instant claim 35.

Paau et al. differs from the claimed invention in that it does not expressly disclose that at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species.

Papavizas discloses that new strains and biotypes of *Trichoderma viride* and *Trichoderma harzianum* have been developed that are resistant to certain fungicides by exposing them to gamma/ultraviolet radiation (column 1, lines 13-21).

At the time the invention was made, it would have been obvious to have exposed any of the *Trichoderma* species of Paau et al. to radiation prior to combining them to create the fungal inoculant. One of ordinary skill in the art would have been motivated to do this since it would have resulted in strains more resistant to other fungicides, including any fungicides possibly released by any of the other *Trichoderma* species.

Paau et al. also differs from the claimed invention in that it does not expressly disclose that the biocontrol fungus mixture comprises *Trichoderma* strains identified as T 22 (KRL-AG 2 or Rifai), Tr 115, or Tr 116.

Harman discloses the *T. harzianum* strain T-22 organism, which is also known as KRL-AG2 (page 377, second column, second paragraph). This biocontrol agent controls the growth of fungi, thereby serving as a suitable substitute for other fungicides and as an agent for plant growth (page 385, first column and Figures 9 and 10).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the *T. harzianum* strain used in the Paau invention with the *T.*

harzianum strain disclosed by Harman. One of ordinary skill in the art would have been motivated to do this since *T. harzianum* strain T-22 is effective against fungi and serves as a biocontrol agent, thus sharing properties with the *T. harzianum* strain of the Paau invention. Moreover, the strains are members of the same species, thus sharing other properties. One of ordinary skill would have reasonably expected that the substitution would have been suitable as a component in a composition for protecting crop plants from fungal damage.

In sum, claims 21-23, and 35 are rendered obvious. A holding of obviousness is clearly required.

Claims 21-23, 29, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCabe et al. or Paau et al. (Hermosa et al. & ATCC catalog) as applied to claims 21-23 and 35 above, and further in view of Howell et al. (Journal of Cotton Science, 1997, 1: 15-20) and Fisher et al. (Proc. Okla. Acad. Sci. 1983, 63: 100-101).

As discussed above, McCabe et al., and Paau et al. (Hermosa et al. & ATCC catalog) render claims 21-23 and 35 obvious. However, these references do not expressly disclose that the compositions of these references include a latex base.

Howell et al. discloses the treatment of seeds with a coating of latex sticker and a *Trichoderma virens* preparation (page 17, first column, first paragraph), along with metalaxyl. Thus, the treatment layers on the seeds are considered a composition comprising *T. virens* and a latex base. It was found that such a treatment was effective in acting as a fungicide (abstract).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to have included latex in the compositions disclosed by McCabe et al. and Paau et al.

(Hermosa et al. & ATCC catalog). One of ordinary skill in the art would have been motivated to do this since one of ordinary skill in the art would have recognized the suitability of including latex in a seed coating. Moreover, latex included in the McCabe and Paau compositions would not have inhibited the antifungal activity of the *Trichoderma* species present in said compositions. Thus, claim 29 is rendered obvious.

McCabe et al. and Paau et al. (Hermosa et al. & ATCC catalog) also differ from the claimed invention in that they do not expressly disclose that the *Trichoderma* fungi were cultured on micronized oat.

Fisher et al. discloses *Trichoderma* fungi as biocontrol agents (page 100, first three paragraphs). The *Trichoderma* fungi may be grown on oats (page 100, last line).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have grown the *Trichoderma* fungi used in McCabe et al. and Paau et al. on oats. One of ordinary skill in the art would have been motivated to do this since oat is a suitable composition for culturing *Trichoderma* fungi. Moreover, it would have been obvious to have used any form of oats, including micronized oats, since the substitution of one known form of oats for another would have yielded oats with similar properties which would have been expected to have served as suitable compositions for culturing *Trichoderma* fungi.

However, claim 42 is a product-by-process claim. MPEP 2113 indicates that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” Therefore, claim 42 is rendered obvious.

A holding of obviousness is clearly required.

Claims 21-23, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paau et al., Hermosa et al., ATCC catalog, Papavizas and Harman.

As discussed above, Paau et al., Hermosa et al., ATCC catalog, Papavizas, and Harman render claims 21-23, and 35 obvious. However, these references do not expressly disclose the use of the “volley technique” or specific types of equipment used in applying the biocontrol composition to plants/seeds/soil. Further still, Paau et al. does not teach the applied dose recited in claim 34 under examination.

At the time the invention was made, it would have been obvious to have applied the Paau composition to plants and seeds using various techniques, including the “volley technique.” One of ordinary skill in the art would have been motivated to do this since Paau et al. indicates that the composition can be sprayed on the plant seed, soil, or plant (column 5, lines 8-10), and it is clear that spraying can be performed with various types of machines. Thus, instant claim 33 is rendered obvious. Moreover, the selection of suitable doses of the biocontrol composition would have a matter of routine experimentation on the part of the artisan of ordinary skill in the art. Thus, instant claim 34 is rendered obvious.

A holding of obviousness is clearly required.

Claims 21-23, 29, 35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richard (US 4,678,669) in view of Papavizas, Howell et al. and Fisher et al.

Richard discloses a method for controlling soil-borne pathogens in plants wherein plants are treated with a mixture comprising a viable culture of *Trichoderma*, such as *Trichoderma viride* (alternative spelling of *T. viridae*) and *Trichoderma polysporum* (claims 1 and 2). Note that any plant can be considered food. Also, the mixture can be of two strains of *T. viride* and one strain of *T. polysporum* (claim 3). Any one of the *T. viride* strains can be considered "a variation thereof" of a *T. viride*. Since "holomorph" encompasses all fungi, limitations of instant claim 23 are taught by the reference.

Richard differs from the claimed invention in that it does not expressly disclose that at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species.

Papavizas discloses new strains and biotypes of *Trichoderma viride* and *Trichoderma harzianum* have been developed that are resistant to certain fungicides by exposing them to gamma/ultraviolet radiation (column 1, lines 13-21).

At the time the invention was made, it would have been obvious to have exposed any of the *Trichoderma* species of Richard to radiation prior to combining them to create the fungal mixture. One of ordinary skill in the art would have been motivated to do this since it would have resulted in strains more resistant to other fungicides, including any fungicides possibly released by any of the other *Trichoderma* species. Thus, claims 21-23 and 35 are rendered obvious.

Richard also differs from the claimed invention in that it does not expressly disclose that the Richard composition includes a latex base.

Howell et al. discloses the treatment of seeds with a coating of latex sticker and a *Trichoderma virens* preparation (page 17, first column, first paragraph), along with metalaxyl. Thus, the treatment layers on the seeds are considered a composition comprising *T. virens* and a latex base. It was found that such a treatment was effective in acting as a fungicide (abstract).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to have included latex in the composition disclosed by Richard. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill in the art would have recognized the suitability of including latex in a seed coating. Moreover, latex included in Richard composition would not have inhibited the antifungal activity of the *Trichoderma* species present in said compositions. Thus, claim 29 is rendered obvious.

Richard also differs from the claimed invention in that it does not expressly disclose that the *Trichoderma* fungi were cultured on micronized oat.

Fisher et al. discloses *Trichoderma* fungi as biocontrol agents (page 100, first three paragraphs). The *Trichoderma* fungi may be grown on oats (page 100, last line).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have grown the *Trichoderma* fungi used in Richard on oats. One of ordinary skill in the art would have been motivated to do this since oats are a suitable composition for culturing *Trichoderma* fungi. Moreover, it would have been obvious to have used any form of oats, including micronized oats, since the substitution of one known form of oats for another

would have yielded oats with similar properties which would have been expected to have served as suitable compositions for culturing *Trichoderma* fungi.

However, claim 42 is a product-by-process claim. MPEP 2113 indicates that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” Therefore, claim 42 is rendered obvious.

A holding of obviousness is clearly required.

Claims 21-24, 33-35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinbergen (WO 97/31879) in view of Papavizas, Harman, and Fisher et al.

Reinbergen discloses a liquid composition comprising a microbial spore or culture preparation and a solution having a colloidal nature (claim 8) wherein the microbial spore or culture preparation is selected from a group consisting of spores of cultures from *Trichoderma* and mixtures thereof (claim 10). Furthermore, the *Trichoderma* species is selected from a group consisting of *T. harzianum*, *T. polysporum*, *T. konigii*, *T. viride*, *T. hamatum* and **mixtures thereof** (claim 12). Note that *T. viride* is considered an alternative spelling of *T. viridae*. Also, *T. hamatum* can be considered a “variation” of *Trichoderma* species *T. viridae*, *T. polysporum*, *T. longibratum*, *T. harzianum* or *T. konigii*, since *T. hamatum* is a species of the same genus as the fungi listed above, the term “variation” is broad, and since “holomorph” in instant claim 23 encompasses all fungi. Therefore, Reinbergen meets limitations in instant claims 21-24.

Furthermore, the Reinbergen invention can be used for food products (page 5, lines 21-23), thus teaching the limitations of instant claim 35.

Reinbergen differs from the claimed invention in that it does not expressly disclose that at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species.

Papavizas discloses that new strains and biotypes of *Trichoderma viride* and *Trichoderma harzianum* have been developed that are resistant to certain fungicides by exposing them to gamma/ultraviolet radiation (column 1, lines 13-21).

At the time the invention was made, it would have been obvious to have exposed any of the *Trichoderma* species of Reinbergen to radiation prior to combining them to create the Reinbergen composition. One of ordinary skill in the art would have been motivated to do this since it would have resulted in strains more resistant to other fungicides, including any fungicides possibly released by any of the other *Trichoderma* species. Thus, claims 21-24 and 35 would have been rendered obvious.

Reinbergen also differs from the claimed invention in that it does not expressly disclose that the composition comprises *Trichoderma* strains identified as T 22 (KRL-AG 2 or Rifai), Tr 115, or Tr 116.

Harman discloses the *T. harzianum* strain T-22 organism, which is also known as KRL-AG2 (page 377, second column, second paragraph). This biocontrol agent controls the growth of fungi, thereby serving as a suitable substitute for other fungicides and as an agent for plant growth (page 385, first column and Figures 9 and 10).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the *T. harzianum* strain used in the Reinbergen composition with the *T. harzianum* strain disclosed by Harman. One of ordinary skill in the art would have been motivated to do this since *T. harzianum* strain T-22 is effective against fungi and serves as a biocontrol agent, which are properties of the Reinbergen compositions. Moreover, the strains are members of the same species, thus sharing other properties. The person of ordinary skill in the art would have recognized the suitability of using any strain of the *T. harzianum* species in the Reinbergen composition.

Reinbergen also differs from the claims in that Reinbergen does not expressly disclose the use of the “volley technique” or specific types of equipment used in applying the biocontrol composition to plants/seeds/soil. Further still, Reinbergen does not teach the applied dose recited in claim 34 under examination.

At the time the invention was made, it would have been obvious to have applied the Reinbergen composition to plants and seeds using various techniques, including the “volley technique.” One of ordinary skill in the art would have been motivated to do this since Reinbergen indicates that the composition (marketed as CompanionTM and Companion 2TM) can be sprayed on plots (page 14, lines 7-9 and lines 19-20), and it is clear that spraying can be performed with various types of machines. Thus, instant claim 33 is rendered obvious. Moreover, the selection of suitable doses of the Reinbergen composition would have been a matter of routine experimentation on the part of the artisan of ordinary skill in the art. Thus, instant claim 34 is rendered obvious.

Finally, Reinbergen also differs from the claimed invention in that it does not expressly disclose that the *Trichoderma* fungi were cultured on micronized oat.

Fisher et al. discloses *Trichoderma* fungi as biocontrol agents (page 100, first three paragraphs). The *Trichoderma* fungi may be grown on oats (page 100, last line).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have grown the *Trichoderma* fungi used in Reinbergen on oats. One of ordinary skill in the art would have been motivated to do this since oats are a suitable composition for culturing *Trichoderma* fungi. Moreover, it would have been obvious to have used any form of oats, including micronized oats, since the substitution of one known form of oats for another would have yielded oats with similar properties which would have been expected to have served as suitable compositions for culturing *Trichoderma* fungi.

However, claim 42 is a product-by-process claim. MPEP 2113 indicates that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” Therefore, claim 42 is rendered obvious.

A holding of obviousness is clearly required.

Claims 21-26, 33-35, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinbergen, Papavizas, Harman, and Fisher et al. as applied to claims 21-24, 33-35, and 42 above, and further in view of Gromovkyh et al. (Proceedings of 1999 Annual

International Research Conference on Methyl Bromide Alternatives and Emissions Reductions, <http://www.epa.gov/ozone/mbr/airc/1999/>, last updated June 6, 2002).

As discussed above, Reinbergen, Papavizas, Harman, and Fisher et al. render claims 21-24, 33-35, and 42 obvious. However, these references do not expressly disclose that *Trichoderma longibrachiatum* is included in the mixture of *Trichoderma* species taught in the Reinbergen liquid composition, wherein the Reinbergen liquid composition already teaches a mixture comprising *T. viridae* and *T. harzianum*.

Gromovkyh et al. discloses that five of the most promising isolates against certain pathogenic fungi were identified. These five strains corresponded to the species *T. viride* (*T. viridae*), *T. harzianum*, and *T. longibrachiatum*, among others. See first page, "Materials and methods." All of these tested strains demonstrated antagonistic activity against a particular pathogenic fungus species (second page, "Results and discussion").

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included *T. longibrachiatum* as one of the *Trichoderma* species in the mixture included in the Reinbergen liquid composition. One of ordinary skill in the art would have been motivated to do this because of the antifungal properties exhibited by *T. longibrachiatum*, wherein said antifungal properties are the properties desired for the Reinbergen liquid composition. Additionally, the selection of particular proportions of the different *Trichoderma* species present in the Reinbergen composition would have been a routine experimentation on the part of the artisan of ordinary skill in the art. Therefore, claims 25 and 26 are rendered obvious by the references. Claim 41 is also rendered obvious given the teachings of Papavizas. A holding of obviousness is clearly required.

Claims 21-28, 33-35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinbergen, Papavizas, Harman, and Fisher et al. as applied to claims 21-24, 33-35, and 42 above, and further in view of Panizzi et al. (Journal of Ethnopharmacology. February 2002. 79: 165-168).

As discussed above, Reinbergen, Papavizas, Harman, and Fisher et al. render claims 21-24, 33-35, and 42 obvious. However, these references do not expressly disclose that the *Trichoderma* composition further comprises a vegetal extract of bacteriostatic and/or bactericidal nature, or that this vegetal extract is a *Rubus sp.* hydro-alcoholic extract.

Panizzi et al. discloses that a crude methanolic extract of *Rubus ulmifolius* possesses “high antimicrobial properties on bacteria and fungi” (page 165, first column, last paragraph).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included an alcoholic extract of *R. ulmifolius* in the Reinbergen *Trichoderma* composition. One of ordinary skill in the art would have been motivated to do this since it would have further increased the antifungal activity of the *Trichoderma* composition, acting on bacteria or fungi which are not acted on by the *Trichoderma* species included in the composition. A holding of obviousness is clearly required.

Claims 21-24, 29, 33-35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinbergen, Papavizas, Harman, and Fisher et al. as applied to claims 21-24, 33-35, and 42 above, and further in view of Howell et al.

As discussed above, Reinbergen, Papavizas, Harman, and Fisher et al. render claims 21-24, 33-35, and 42 obvious. However, they do not expressly disclose that the *Trichoderma* composition includes a latex base.

Howell et al. discloses the treatment of seeds with a coating of latex sticker and a *Trichoderma virens* preparation (page 17, first column, first paragraph), along with metalaxyl. Thus, the treatment layers on the seeds are considered a composition compromising *T. virens* and a latex base. It was found that such a treatment was effective in acting as a fungicide (abstract).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to have included latex in the *Trichoderma* composition disclosed by Reinbergen. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill in the art would have recognized the suitability of including latex in a seed coating. Moreover, latex included in the composition would not have inhibited the antifungal activity of the *Trichoderma* species present in said composition. A holding of obviousness is clearly required.

Claims 21-24, 33-35, 39, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinbergen, Papavizas, Harman, and Fisher et al. as applied to claims 21-24, 33-35, and 42 above, and further in view of Toet et al. (US 5,330,912) and Yeoh et al. (World Journal of Microbiology and Biotechnology. 1995. 11(6): 678-680).

As discussed above, Reinbergen, Papavizas, Harman, and Fisher et al. render claims 21-24, 33-35, and 42 obvious. However, they do not expressly disclose steps for preparing the *Trichoderma* composition, wherein trays are sowed with *Trichoderma* species in the form of reproductive original units, and then harvested by mechanical means.

Toet et al. discloses a method for producing *Trichoderma harzianum* "...in a form suitable for adding directly to soil to protect plants from pathogenic fungi..." (claim 1). This method comprises inoculating (sowing) trays containing culture medium with *Trichoderma harzianum* spores. The culture is allowed to grow, and the incubated product is dried. See claim 1. Note that a full-scale plant can be constructed in order to perform this method (Example III at columns 3 and 4), wherein the trays containing the inoculated product can be emptied onto drying racks (column 4, lines 3-5). Thus, the resulting inoculated product is harvested by mechanical means.

Yeoh et al. discloses growing strains of *Trichoderma* fungi in a culture medium comprising cassava-root extract, which is a vegetal extract. See abstract.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the Reinbergen *Trichoderma* composition by the methods disclosed by Toet et al, wherein trays containing culture medium are inoculated with spores of all *Trichoderma* species included in the composition, and the biomass is harvested by mechanical means. Moreover, it would have been obvious to have included vegetal extracts in the culture medium. One of ordinary skill in the art would have been motivated to have used the methods disclosed by Toet et al. since these had been shown to be successful in obtaining one of the species included in the Reinbergen composition, *Trichoderma harzianum*, and the *Trichoderma* species is obtained in a form suitable for protecting plants from pathogenic fungi, a desired property.

Furthermore, one of ordinary skill in the art would have been motivated to have used vegetal extracts, such as root extracts, in the culture medium since it would have permitted

Trichoderma growth, and was recognized as being suitable for inclusion in *Trichoderma* culture medium by Yeoh et al. Moreover, since the culture medium used in Toet et al. comprises of spent grain, crushed maize cobs, and bran, one of ordinary skill in the art would have expected that the extracts of these products would have contained the nutrients needed for *Trichoderma* growth. Thus, claim 39 under examination is rendered obvious.

Additionally, it would have been a matter of routine experimentation to have varied the quantities of each species present in the prepared composition, including the quantities recited in claim 40 under examination. A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed July 8, 2009, have been fully considered but they are not persuasive. First, with respect to the enablement rejection, the applicant asserts that the list of entities that sell the Tr 115 and Tr 116 microorganisms shows that the microorganisms are commercially available and are known and readily available to the public. However, it is unclear that the microorganisms were publicly available without restriction. The office action indicates that an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement.

Also, it is unclear whether deposits were made under the terms of the Budapest Treaty. As indicated in 37 CFR 1.803(a), an acceptable depository is a deposit made in any Internal Depository Authority (IDA) as established under the Budapest Treaty, or any other depository

recognized to be suitable by the Office (determined by the Commissioner). Of the list of entities provided in the arguments, it is noted that only the DSMZ and NCAIM are IDAs recognized under the Budapest Treaty. Moreover, the mere fact that a deposit has been made in one of the depositories does not mean that the terms of the deposit meet either the requirements of the Budapest Treaty or the deposit regulations.

Also, as pointed out in MPEP 24041.01, “The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available.” Further still, for each deposit made pursuant to the regulations, the specification should contain the accession number for the deposit, the date of the deposit, description of the deposited biological material sufficient to specifically identify it and to permit examination, and the name and address of the depository.

With respect to the indefiniteness rejections, the applicant asserts that one of ordinary skill in the art would have understood a “variation” of a species to mean different subspecies, subtypes, or strains. However, the art does not provide a definition for “variation of a species” and the specification as filed does not limit “variation” to only mean “different subspecies, subtypes, or strains” of a species. The applicant asserts that the specification provides examples of variations in paragraph 47 of the US-PGPUB of the application (second paragraph on page 8 of the specification as filed). However, paragraph 47 lists the species *T. harzianum*, *T. viridae*, *T. polysporum*, *T. longibratum*, and *T. koningii*, and indicates “variations of these obtained in the laboratory **and identified as** T 22, Tr 115, Tr 116, KRL-Ag 2 (Rifai), including holoforms as *Hypocrea*, *Podostroma*” (emphasis added). Clearly T 22, Tr 115, Tr 116, KRL-Ag 2 (Rifai), and

“holoforms as Hypocrea, Podostroma” are not examples, but are the only recognized “variations” provided in the disclosure.

The applicant also asserts that one skilled in the art would understand the phrase “cicatrizing paint” as paint capable of wound healing. However, “cicatrizing paint” is not considered a term recognized in the prior art. If interpreted in its context, it is made further confusing given that the claim recites “pruning a cicatrizing paint.” From its context, the definition of a “cicatrizing paint” is unclear. It is noted that in the prior art, there are “pruning paints” which cover pruning wounds of trees. See column 1, lines 18-23 of Sedun (US 5,395,851).

McCabe speaks of “viable propagules,” which the applicant asserts does not indicate that the *Trichoderma* are alive and living in a manner that does not annihilate the other. However, Jackson (US 5,968,808) indicates that “propagules are any living cells from a fungus that will propagate such as spores, mycelium or other fungal biomass” (column 6, lines 39-41). Spores, described as propagules, can be considered live (Addeo et al., US 5,527,570, column 7, line 3). Moreover, “viable” can mean “living” as Errede et al. (US 4,722,898) indicates that “viable cell” means any living organism...including...fungal...forms” (column 2, lines 63-65). Thus, the *Trichoderma* in McCabe et al. are live.

Also, when the corn plant that has been treated with the McCabe composition (by application of the composition to the seeds or introduced into the seed furrows) is grown, “...a mycorrhizated culture of the fungi will develop in the root system of the corn plant as it grows” (column 3, lines 19-21). Moreover, McCabe et al. teaches that “sufficient fungal growth so that corn grain yield is increased” is sought (column 3, lines 55-57) and that “the fungus grows in

cultivation..." (column 4, line 51). The indication that there is a culture of fungi and fungal growth provides evidence that the fungi are alive. Even when present underground along with the plant, the fungi mixture is considered a "bactericidal, bacteriostatic and fungicidal composition."

The *Trichoderma* are living in the mixtures disclosed in McCabe et al., thus the reference provides evidence that the species do not annihilate each other. Moreover, the prior art is presumed to be operable/enabling. As pointed out in MPEP 2121, section I, "...the burden is on applicant to provide facts rebutting the presumption of operability." The applicant has not provided evidence to demonstrate that the two or more live *Trichoderma* in McCabe et al. annihilate each other. MPEP 2145, section I states that "The arguments of counsel cannot take the place of evidence in the record."

The applicant asserts that Richard is directed to immunizing commensals that grow internally in a plant or other host and thus are not directed to a composition as recited in instant claims 21-23. However, claims 21-23 broadly recite a composition, which can encompass even a plant as a whole containing the fungi. With respect to claim 35, the recitation of "**applying** the composition **to...foods**" (emphasis added) encompasses application in a variety of ways, including the insertion of the microorganisms into a plant. "Applying to" has a different meaning than "applying onto." Moreover, the fungi composition is indeed applied onto foods since it can be sprayed onto fruits such as grapes (column 7, lines 19-26 and column 9, lines 7-10). Thus, claim 35 is indeed taught by the reference.

With respect to Reinbergen, the applicant argues that Reinbergen does not teach two or more live *Trichoderma* since they are present as spores. However, as pointed out above, spores

can be considered live (Addeo et al., US 5,527,570, column 7, line 3). Also, the applicant has not presented evidence to show that the microbes will indeed compete or annihilate each other. MPEP 2145, section I states that "The arguments of counsel cannot take the place of evidence in the record." Moreover, the prior art is presumed to be operable/enabling. As pointed out in MPEP 2121, section I, "...the burden is on applicant to provide facts rebutting the presumption of operability."

In response to applicant's argument that the examiner's conclusion of obviousness with respect to combining Reinbergen and Gromovykh is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Finally, Papavizas has been introduced and combined with the references to render obvious the new limitation that at least one of the *Trichoderma* species was transformed by exposure to radiation before being contacted with another *Trichoderma* species.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef